

Applicants : Tove Ringerike et al.  
Serial No. : 10/577,268  
Filed : April 26, 2006  
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REMARKS

Claims 4, 8, 9, 11-13, 15, 16, 25, and 44-52 are pending in the subject application, with claims 24 and 52 withdrawn from consideration. Applicants have not added, cancelled, or amended any claims herein.

Election/Restriction

On page 2 of the June 9, 2010 Office Action, the Examiner withdrew the species election requirement for claims 4, 8, 44, and 45 and rejoined the species of SEQ ID NOs: 1-35. The Examiner withdrew claim 52 from consideration as being directed to the invention of non-elected group II, there being no allowable generic or linking claim.

In response, Applicants look forward to the rejoinder of claims 24 and 52 upon the allowance of claims 9 and 46.

Priority

On page 3 of the June 9, 2010 Office Action, the Examiner acknowledged Applicants' claim of priority to PCT/PL2003/00098, but stated that Applicants have not filed a certified copy of the application as required by 35 U.S.C. § 119(b).

In response, Applicants will submit a certified copy of PCT/PL2003/00098 as soon as one is obtained.

Objections to the Specification

On page 4 of the June 9, 2010 Office Action, the Examiner objected to the specification because of the following informalities: page 16, line 15 contained a typographical error "trough," page 25, line 16 contained the typographical/grammatical error "details," and page 41, line 25

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contained a typographical error in the term "previos." The specification was also objected to because it failed to state the date of deposit of the cell lines recited therein, and failed to stated the complete name and address of the depository.

In response, Applicants have amended the specification to correct the above-identified typographical errors and to insert the date of deposit and the complete name and address of the depository where the disclosed cell lines have been deposited.

**Claims Rejected Under 35 U.S.C. §112, First Paragraph**

On page 4 of the June 9, 2010 Office Action, the Examiner rejected claims 9, 11-13, 15-16, and 46-51 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention, because the specification allegedly does not provide evidence that the claimed biological materials are (1) known and readily available to the public, (2) reproducible from a written description, or (3) deposited.

In response, Applicants note that only claims 16 and 51 recite specific cell lines. Accordingly, Applicants attach hereto, as **Exhibits 1-7**, deposit certificates received from the European Collection of Cell Cultures (ECACC) indicating deposit in accordance with the Budapest Treaty of 1977 of each of the following cell lines listed in Table III and recited by claims 16 and 51: C/pCA-EGFP-F/2 (deposited in ECACC, Accession No. 3091201), C/p1-5'3'TNF $\alpha$ -dEGFP/2 (deposited in ECACC, Accession No. 3091202), EL/pCA-dEGFP/9 (deposited in ECACC, Accession No. 3091203), EL/p1-5'IL2-dEGFP/6 (deposited in ECACC, Accession No. 3091204), EL/p2-5'IL4-dEGFP/2 (deposited in ECACC, Accession No. 3091205), EL/p1-5'IFN $\gamma$ -dEGFP/3 (deposited in ECACC, Accession No.

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3091206), EL/p2-5'IL10-dEGFP/5 (deposited in ECACC, Accession No. 3091207), and J/p4-5'IL1  $\beta$ -dEGFP/4 (deposited in ECACC, Accession No. 3091208). Applicants will submit a deposit certificate for the EL/p1-5'IL2-dEGFP/6 cell line (ECACC Accession No. 3091204) as soon as a copy is obtained.

Applicants have amended the specification hereinabove to indicate the date of deposit, as well as the complete name and address information of the ECACC depository. In addition, Applicants state that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent from the subject application, and that the deposit will be replaced if viable samples cannot be dispensed by the depository.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

**Claims Rejected Under 35 U.S.C. §101**

On page 7 of the June 9, 2010 Office Action, the Examiner rejected claims 9, 11-13, 15-16, and 46-51 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. The Examiner alleged that the term "single-celled host" is not defined by the specification, but asserted that the term is partially defined by claim 11, for example, as encompassing mammalian cells as well as eukaryotic cell lines. The Examiner asserted that since mammals are not single-celled organisms, and since the claim distinguishes mammalian cells from eukaryotic cell lines, the recitation of "single-celled host" reads on a cell that is present in a human being, which is non-statutory subject matter.

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In response, Applicants respectfully submit that interpreting "single-celled host" to read on a human being is an unreasonable construction of the claims. For the sake of clarity, Applicants hereby disavow any interpretation of the term "single-celled host" which would read on a cell present in a human being. See, *Purdue Pharma L.P. v. Endo Pharm., Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) ("a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution").

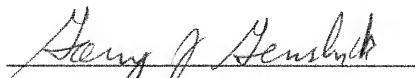
Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than the \$1,110.00 fee for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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<b>Certificate of Transmission</b>	
I hereby certify that this correspondence is being transmitted via the Electronic Filing System (EFS) to the U.S. Patent and Trademark Office on <u>December 9, 2010</u> .	
 Adam C. Krol	Date Reg. No. 64,351